

Amendments to the Drawings:

Corrections to the drawings are provided as new Sheet 5 showing new Figures 5 and 6, and new Sheet 6 showing new Figure 7.

REMARKS

I. Summary of Claim Status

Claims 31-53, 55, 60 and 62-67 remain in this case.

It is noted that Claims 54-59 and 61 would be allowable if rewritten to overcome the rejections under 35 U.S.C. §112, second paragraph, and to include all the limitations of the base claim and any intervening claims. These claims have been so amended, with claims 54, 56-59 and 61 cancelled without prejudice, and rewritten as new claims 62-67 with claim 55 continued and now dependent on new claim 62. All these claims are believed to be now in condition for allowance.

II. Objection to the Drawings

The drawings have been objected to for the requirement to show every feature of the invention specified in the claims. Claim 34 recited that the cleft longitudinally cuts both front and rear portions. To show this structure new Figure 7 is proposed on New Sheet 6. This is further described in the amendment to the specification on page 3 and this is supported in the original specification on page 4, lines 12-14 and page 7, lines 23-29. Claim 34 defines another embodiment of the new implantable device where from the central hole in the central portion the cleft is applied to the front and rear, producing a set of halves. As described on page 4, lines 12-14 and page 7, lines 23-29, these cleaved halves are surgically implanted (front and rear ends being fixed) and then they are rejoined. Claims 35 and 36 recite that the cleft cuts transversely the right central portion, or the left central portion respectively. In response to this

rejection, New Sheet 5 of the drawings showing new Figures 5 and 6 has been attached hereto. These figures show the cleft cutting the right central portion and the left central portion respectively, thus corresponding to Claims 35 and 36. This is not new matter because such description was disclosed in the specification on page 4, lines 15-17.

An additional objection to the drawings on page 3, paragraph 3 of the Office Action concerns the need for individual figure numbers for each of the figures. This has been corrected in the Replacement Sheets 1-3 of the drawings. Specifically, for example, Sheet 1 referring to Figure 1 now has been amended to refer to Figure 1A and Figure 1B. Similar changes are made in Sheets 2 and 3 now Replacement Sheets 2 and 3. Formal drawings will be submitted as soon as possible to further replace the current sheets of drawings.

III. Objections to the Specification

On page 3 of the Office Action in paragraph 4 there is an objection to the specification as regards omitted units for numerical distances and requirement for correction. This correction has been made as indicated in the previous amendment to the specification, specifically in line 2. The units of centimeters has been added. It is submitted that the unit of centimeters is totally obvious in view of the inclusion of centimeter units throughout the entire specification and claims and also in the very sentence to which the objection has been made.

IV. Objections to the Claims

Objection to claims found on page 4, paragraph 5 of the Office Action, stating that reference characters should be omitted. Correction responsive to the objections have been made above in the amendments to the claims.

On page 4, paragraph 8 of the Office Action, Claims 31-61 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and claim the subject matter which the applicant regards as the invention. Amendments to overcome the objections listed have been made as discussed below.

In Claim 31 the term "may be distinguished" in line 3 has been amended as suggested by the Examiner to "comprising". Also in Claim 31, line 10 we have added a descriptive term "front" before "arms", and in line 5 before "arms" we added an antecedent for "front"; and for consistency we have added the term "rear" before "arms" in line 8.

In Claim 38 the objection to indefiniteness is corrected by the inclusion of "with a reticular or laminar structure" to replace "of organic origin". Claim 38 is now parallel in structure to Claim 37.

Claims 40 and 41 have been objected to as indefinite because "materials of a synthetic nature" are not positively required in Claim 37 on which Claims 40 and 41 depend. This has been corrected by having Claims 40 and 41 amended to each depend on Claim 31 which is not a Markush Group type claim with its indefiniteness.

Claims 42 and 43 have been objected to on indefiniteness because of the omission of certain dimension units. The intent for these units to be centimeters is obvious because other units in this claim include centimeters, and the dimension of

centimeters has been used throughout the specification and in many other claims, and in fact is essentially the only distance dimension used throughout.

Claims 44 and 46 have been objected to for limitations of "the length a-a", "the length b-b", etc. This objection states there is insufficient antecedent basis for this limitation for these claims; however, it is believed that the required antecedent basis appears in the specification on page 4, line 25 through page 5, line 20, wherein the same exact terminology is used.

Claims 45 and 47 have been objected to for indefiniteness as regards "for patients with a large body size" and "for patients with a small size". It is believed that the obvious meaning is patients with larger than average or smaller than average size, as would be reported in a basic or typical anatomy book, and readily understood by a person skilled in the relevant art.

Claims 48-53 and 60 are objected to for incorrect Markush Group limitations. These claims have been amended to include proper Markush terminology of "the group consisting of".

Claims 54-59 and 61 (now Claims 62-67 and 55) are objected to for recitation of "tendinous arch of the levator ani". This objection requests explanation of the location in the body of the anatomical structure in question. The "location" is well known from typical reference books, as listed in Appendix A attached hereto. Also attached is Appendix B which includes color illustrations from Atlas of Human Anatomy by Frank H. Netter, M.D., Copyright 1989 CIBA-GEIGY CORPORATION.

V. Status of the Claims and Rejections on Prior Art

Claims 31-33 and 35-47 are device claims, and Claims 48-61 are method claims, all of which depend upon at least one of the device claims. Of the method Claims 48-61, the following were found allowable if rewritten to include the dependent limitations of the base claim and any intervening claims, these allowable claims being Claims 54-59 and 61.

The first rejection on prior art is found on page 6, paragraph 10 of the Office Action which rejects Claims 31-33, 35-37, 40, 41 and 44-47 under 35 U.S.C. §103(a) as being obvious over EP 0 774 240 ("the '240 patent") in view of U.S. Patent No. 6,436,030 ("the '030 patent"). Claim 31 is the basic independent device claim on which all of the above-mentioned group of claims depend. The '240 patent will be designated herein also as Landgrebe et al., and the '030 patent will be designated also as Rehil.

Landgrebe, et al. has been cited for teaching a flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs having a central body with a trapezoid shape with four arms and other specified features.

In the rejection of Claim 31 the Examiner has recited that Landgrebe et al. satisfies claim language "characterized in that the said two arms (projections 5 and 6) branch off from the front portion (region of corner 2) in opposite directions and are coaxial with each other and parallel to said smaller base (these arms are coaxial when the device is folded in half longitudinally) (emphasis added). These arms are also considered to be parallel to the side portions of the smaller base of the trapezium (see Figure 1)."

It is respectfully submitted that numerous parts of this characterization of Landgrebe et al. "as satisfying terminology in Claim 31" is incorrect. As is known, a trapezoid has a large base at one end and a smaller base at the other end, and diverging walls connecting said bases. The first segment of Claim 31 following the term "characterized" is "In that said two front arms branch off from the front portion in opposite directions." In Landgrebe et al. the two arms both extend upward and not in opposite directions. Arguably they diverge slightly but it is believed unreasonable to assert that they extend in opposite directions.

The next part of Claim 31 states that said two front arms are "coaxial with each other and parallel to said smaller base". Figure 1 of Landgrebe et al. clearly shows that the two arms are not at all coaxial, and furthermore and generally perpendicular to the smaller base, as opposed to parallel to it. The rejection further states in parentheses "these arms are coaxial when the device is folded in half longitudinally".

Claim 31 recites a flat plantable device, and Figure 1 and other figures illustrate the device in such a flat configuration. In that flat state and as recited in Claim 31, the front arms extend in opposite directions and are coaxial to and are parallel to the smaller base. It is believed to be unreasonable to look at the device of Landgrebe et al. and presume that it can be folded, distorted or otherwise reformed into another shape until the two front arms are forced to be coaxial. This is not at all what the Claim 31 states, and the device of Landgrebe et al. in its flat state is totally different from the device of Claim 31 in that its front arms extend upward forming a generally U-shape, whereas the device of the present invention forms a shape more like a starfish with outward extending arms or points.

This rejection further states "these arms are also considered to be parallel to the side portions of the smaller base of the trapezium". This is believed to be incorrect since the front arms of Landgrebe et al. are not only not parallel to any portion of the sides of the trapezium, there is an obtuse angle defined between the actual sides of the trapezium in each arm. Furthermore, the two arms in Landgrebe et al. diverge slightly, and the two sides of the trapezium diverge, and consequently they cannot be said to be parallel.

In the rejection it is stated that Landgrebe et al. does not teach that the central portion has a hole and a cleft. However, Rehil is cited for a hernia patch of square cross-section which does include a central hole and a cleft extending from a hole to one of the side edges of the square shape patch.

It is respectfully submitted that the comments above show that Landgrebe et al. does not come close to showing all of the elements of the claim with the exception of the hole and cleft, so that even a combination of Landgrebe et al. and Rehil, if reasonably combinable, would not result in the structure of Claim 31. A separate argument below urges that Rehil is not an appropriate reference for the structure cited therein, and therefore a reference that is not an obvious or reasonable choice for combination with Landgrebe et al.

VI. Arguments for Lack of Obviousness to Combine Landgrebe et al. and Rehil

First, Rehil pertains to a device for correction hiatal hernia which is not automatically or trivially translated to a device suitable for a device correcting prolapse. Teachings in the Rehil patent for correcting hiatal hernia are unrelated and remote to teachings in Landgrebe et al. for correcting urinary incontinence or for correcting

prolapse of the female pelvic organs. This is due to fundamental physiopathological differences. For example, hiatal hernia is symptomatic when the body is in horizontal position, but these symptoms are reduced with the body is erect. By contrast, prolapsed female pelvic organs behave in the opposite manner. They are symptomatic when the body is erect, but return to their normal positions when the body is prone. Thus, it would not be reasonable to assume one seeking to correct female pelvic organs would be considering a device for correcting hiatal hernia.

Moreover, the organs which these organs which these devices are intended to surround are completely different. The male esophagus and diaphragm muscle cannot reasonably be compared to the female uterus, bladder or rectum. First of all, the esophagus has a variable diameter due to the alimentary bolus transit, while the uterine neck has a smaller and fixed diameter. Thus, a hole surrounding the esophagus needs to have elastic properties well different from that need for holding up the uterine neck.

Finally, Rehil's device is a patch which is laid on the diaphragm and need not support anything while it is useful to prevent the rising of organs. This is a device to correct hiatal hernia, which is found in the region and involves anatomical structures which are diametrically opposed to those treated in applicant's device. By contrast, applicant's device to correct prolapse must be fixed to specific pelvic anatomical structures, namely the arcus tendineous and the sacro spinous ligament, where the device must be able to hold up pelvic organs. Thus, the device as disclosed by Rehil and that of the present invention solve opposite problems, and there is no suggestion or reasonable obviousness for combining the teachings of Landgrebe et al. and Rehil.

To more clearly understand the present invention and how it is distinguished from the cited prior art, a brief description of relevant anatomy, medical issues and surgical procedures is presented in the attached Appendix C below.

Claim 32 recites that a cleft cuts the rear portion of the device and is rejected as obvious over Landgrebe et al. in view of Rahil being cited for a device with a cleft cutting to the rear. It is respectfully submitted that since Claim 32 depends on Claim 31, it will be similarly allowable as Claim 31.

In Claim 33 the cleft longitudinally cuts the front portion. Arguments for Claim 32 are believed equally applicable to Claim 33.

In Claim 35 the cleft cuts to the right. This claim is believed allowable based upon Claim 31 upon which it depends.

In Claim 36 the cleft cuts the left central portion, and the same arguments for allowance apply as for Claim 35.

Claims 37, 40 and 41 are rejected on obviousness to combine Landgrebe et al. and Rehil, in that Landgrebe et al. is asserted to teach material with a reticular or laminar structure is a mixture of monofilament, polypropylene and polyglactin. These claims are dependent on Claim 31 and with their additional limitations are believed allowable based on allowance of Claim 31.

Claims 44-47 include recitation of specific dimensional ranges and specific elements or features of the device. This objection is respectfully traversed, specification of the present application describes devices with the dimensions recited in Claims 44-47. These dimensions have been determined by the inventor and are clearly

specified. The Landgrebe et al. device while it mentions certain dimensions, does not disclose any specific dimensions or group of dimensions the same or comparable or similar to those of these claims, and furthermore because of its totally different shape could not have similar dimensions. Furthermore, no combination of Landgrebe et al. and Rehil could result in devices having dimensions of Claims 44-47.

The rejection asserts that it would be obvious matter of design choice to a person of ordinary skill in the art to modify the dimensions of Landgrebe et al. and Rehil to match those specified in Claims 44-47 because applicant has not disclosed that an implant having those particular claimed dimensions versus dimensions outside of those specified of ranges provides an advantage, as used for a particular purpose or problem. The ranges of dimensions in these rejected claims are precise and specific. It is believed that this is an obvious matter of design choice to a person of ordinary skill in the art is incorrect in part because the Landgrebe et al. device has a shape so totally different from the present claims that even if it were combined with Rehil, namely to add the central hole and the cleft, there would still be a shape totally different from that of the present claims and so that no amount of design choice could result in dimensions as presently claimed.

Claims 38 and 39 are rejected on the combination of Landgrebe et al. and Rehil, further in view of Gabbay. These claims are believed allowable because of their additional limitations in addition to the basic structure being not obvious over Landgrebe et al. and Rehil.

Claims 48-50, 52, 53 and 60 all pertain to a method for surgically implanting the flat implantable device as described in Claim 31. First, this rejection requires that the

combination of Landgrebe et al. in view of Rehil be applied, and this has been traversed above. The rejection, assuming that Landgrebe et al. and Rehil combined render the structure obvious, further asserts that Neisz teaches a method of surgically implanting a flat implantable device for a non-hysterectomized patient suffering a prolapse of the vaginal vault. Arguing it would be obvious to one of ordinary skill in the art to implant the device as described because insertion through the vaginal wall instead of an abdominal incision is less invasive, thus lessens recovery time and pain for the patient.

Rejection of these claims is respectfully traversed for the reasons presented in Section VI of the response above, and the further reason that any teaching from the Niesz reference would not result in the claimed methods and would not be an obvious choice for consideration by one skilled in this art.

Finally, Claim 51 is rejected over Landgrebe et al., Rehil, Sdarois, and Neisz for the same reasons as discussed above. This is respectfully traversed similarly as above, that Landgrebe et al. and Rehil will not result in a device as claimed, and a method of Sdarois and/or Neisz combined with the principal references will not result in the method of Claim 51.

In regard to the rejection of Claims 45 and 47 under 35 U.S.C. §112 for as indefinite regarding "patients with larger body size" and for "patients with smaller body size", the claim structures are clearly intended for patients having pelvic dimensions respectively larger or smaller than the average as reported in any anatomy book.

Regarding the rejection of Claims 54-59 and 61 under 35 U.S.C. §112 as indefinite and requiring clarification on the location of the anatomical structure "tendineous arch of the levator ani", this is well known anatomy books and publications, examples being found in the anatomy books listed in Appendix A attached hereto.

The chart below shows a comparison of disclosures and descriptions in Landgrebe et al. as compared to the present invention. It should be noted that the chart includes four different categories of differences, namely (1) the device purpose, (2) the surgical indication, namely purpose, (3) the method of insertion, and (4) the anchoring mechanism.

Landgrebe et al.'s device is much more limited in function than the applicant's. It supports only the bladder. Its fixation system is in front of the uterus where it is anchored to the pubic ligament. Therefore, its utility is restricted to cases of incontinence and prolapse of the bladder. Moreover, the structure of Landgrebe et al.'s device cannot be adapted to use for correcting total prolapse.

The applicant's device provides a much more complex support. It is ideated to correct total, that is combined prolapse, in other words, of the bladder and uterus and intestine. The anterior anchorage system to the arcus tendineous, the middle system to the cardinal ligaments, and the posterior system to the sacro spinous ligaments make the applicant's device completely different from Landgrebe et al's.

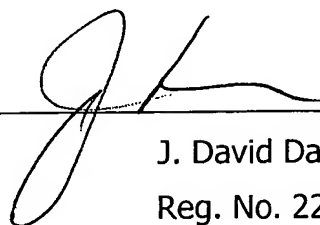
In conclusion, in view of the above amendments to the claims and amendments to the specification, it is believed that all objections have been addressed and all rejections have been considered and clearly traversed. Thus, reconsideration in favorable action is earnestly requested.

Respectfully submitted,

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Attorneys for Applicant

By

A handwritten signature in dark ink, appearing to be 'JD', written over a horizontal line.

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APPENDIX A

APPENDIX A

Female Pelvic Floor Anatomy: The Pelvic Floor, Supporting Structures, and Pelvic Organs, Sender Herschorn, MD, FRCSC, Division of Urology, Sunnybrook and Women's College Health Sciences Center, Toronto, Ontario, Rev Urol. 2004; 6(Suppl5): S2-510;

Anatomic study of arcus tendineous fasciae pelvis; B. Occelli, F. Narducci, J.

Hautefeuille, J.P. Francke, D. Querleu, G. Crepin, M. Cosson; European Journal of Obstetrics & Gynecology and Reproductive Biology, Volume 97, Issue 2, August 2001, pages 213-219; Arcus tendineus fascia pelvis: A further understanding; Todd S. Albright DO, Alan P. Gehrich MD, Gary D. Davis MD, Farzaneh L. Sabi MD and Jerome L. Buller MD. Division of Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics/Gynecology, National Capital Consortium NIH (National Naval Medical Center, Uniformed Services University of Health Sciences, Walter Reed Army Medical Center), Bethesda, MD. American Journal of Obstetrics and Gynecology, Volume 193, Issue 3, September 2005, pages 677-681.

APPENDIX B

ATLAS OF HUMAN ANATOMY

FRANK H. NETTER, M.D.

ATLAS OF HUMAN ANATOMY

by FRANK H. NETTER, M.D.

Sharon Colacino, Ph.D., Consulting Editor

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SUMMIT, NEW JERSEY

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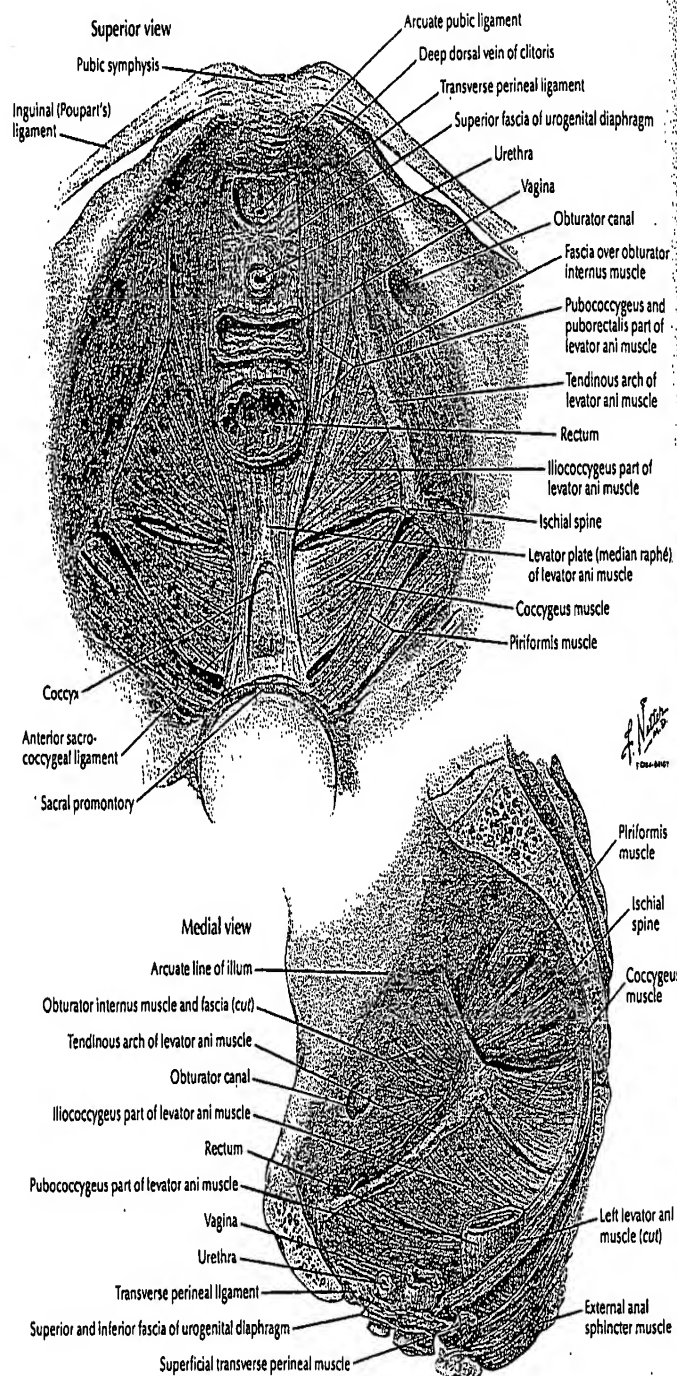
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Binding by The Riverside Group

Composition by U.S. Lithographers

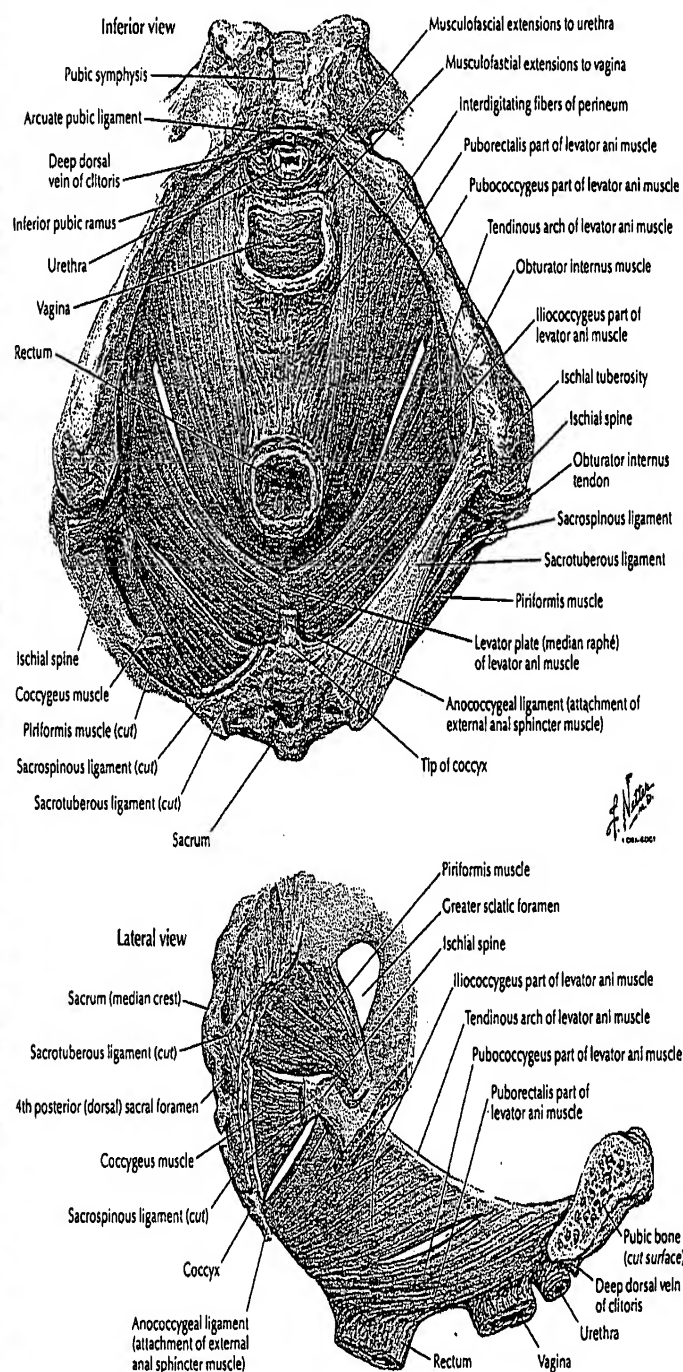
Pelvic Diaphragm: Female

SEE ALSO PLATES 246, 347, 349, 368



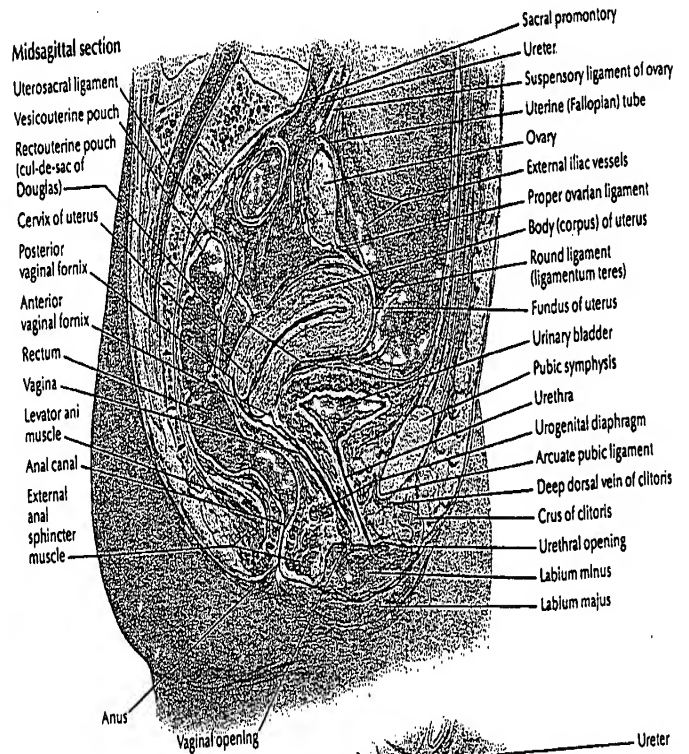
Pelvic Diaphragm: Female (continued)

FOR UROGENITAL DIAPHRAGM SEE PLATE 356

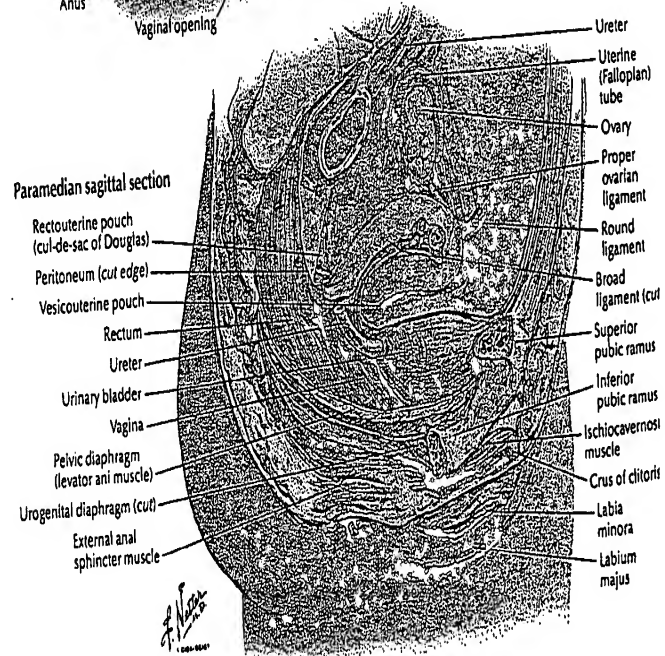


Pelvic Viscera and Perineum: Female

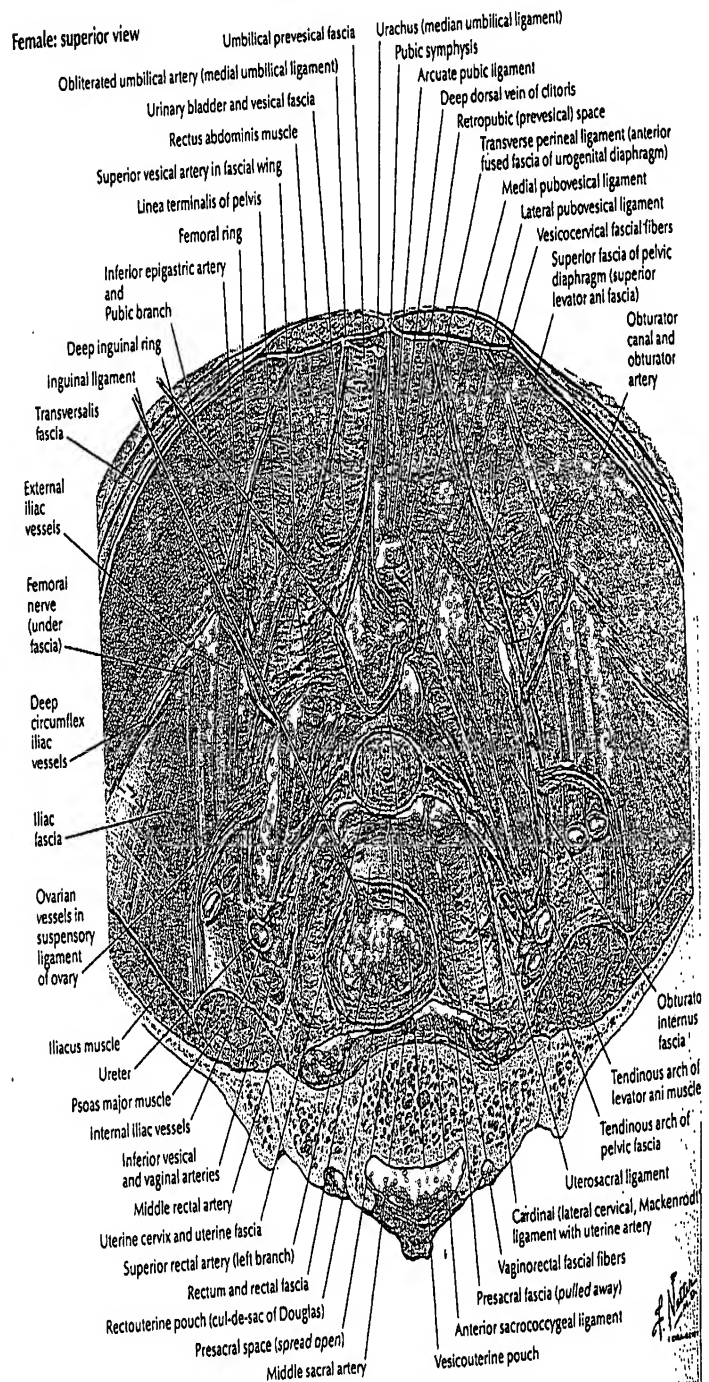
Midsagittal section



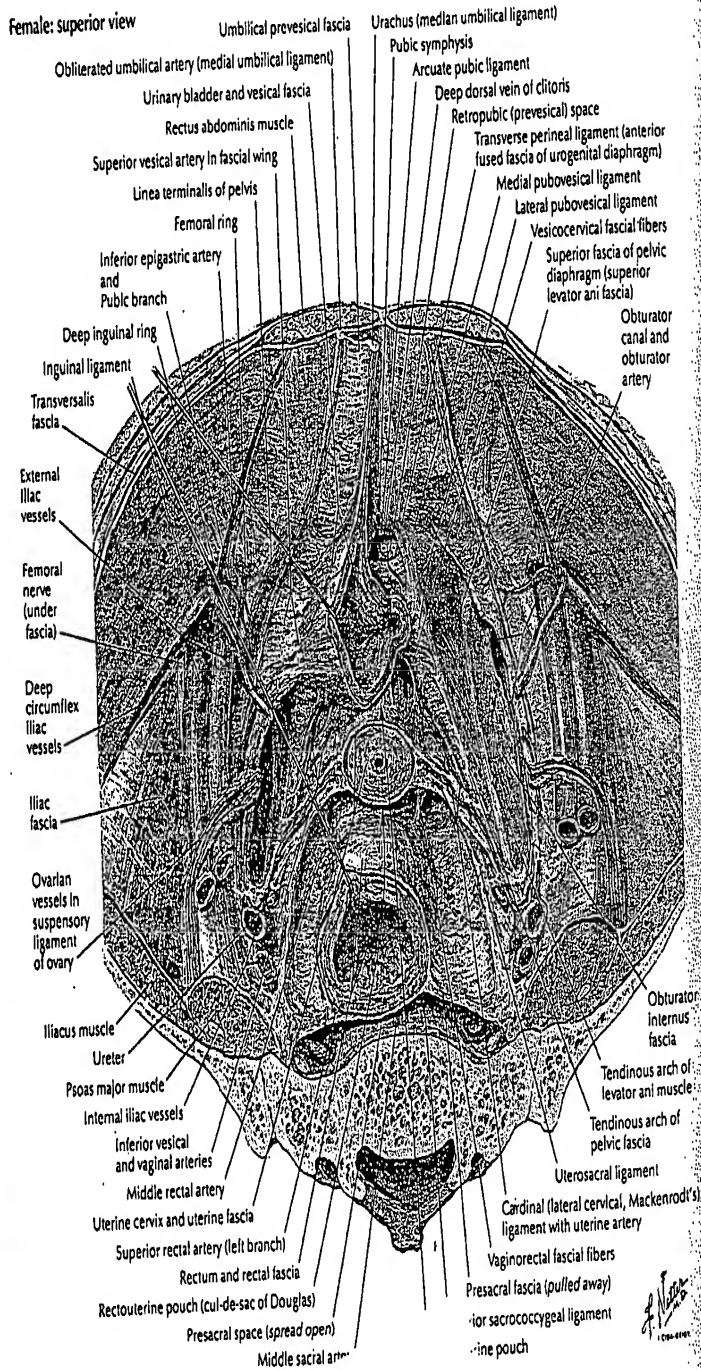
Paramedian sagittal section



Endopelvic Fascia and Spaces

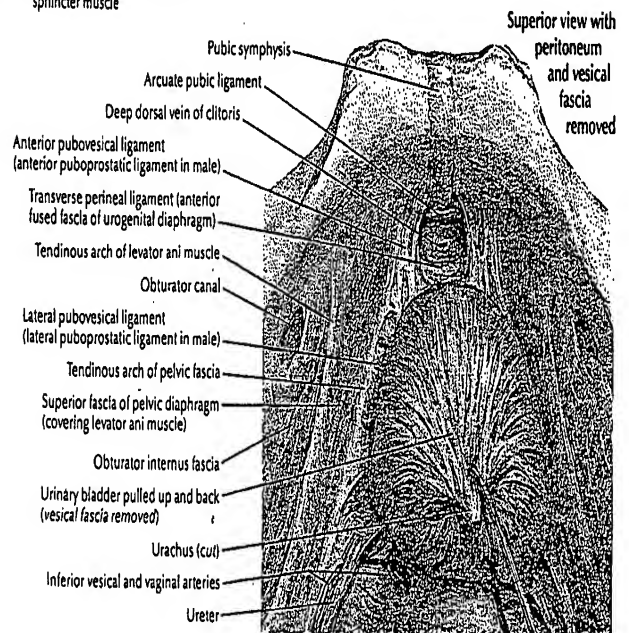
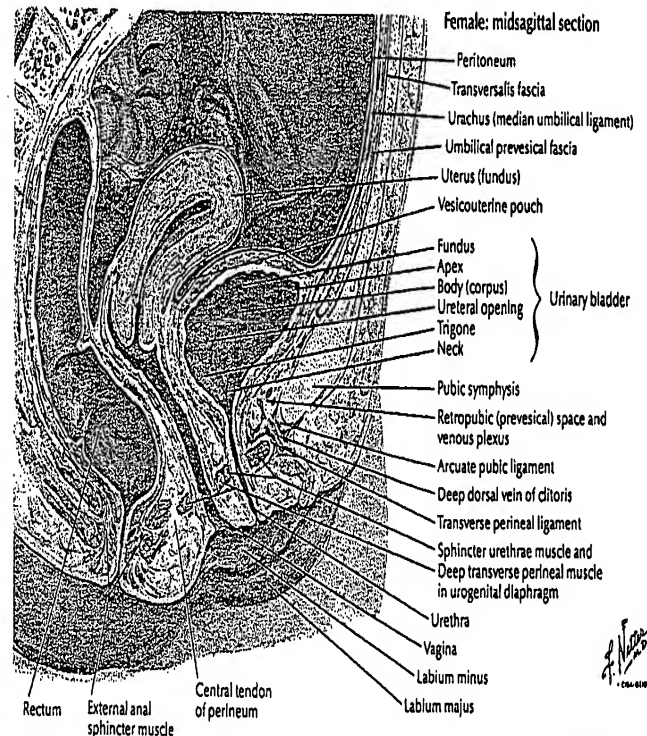


Endopelvic Fascia and Spaces



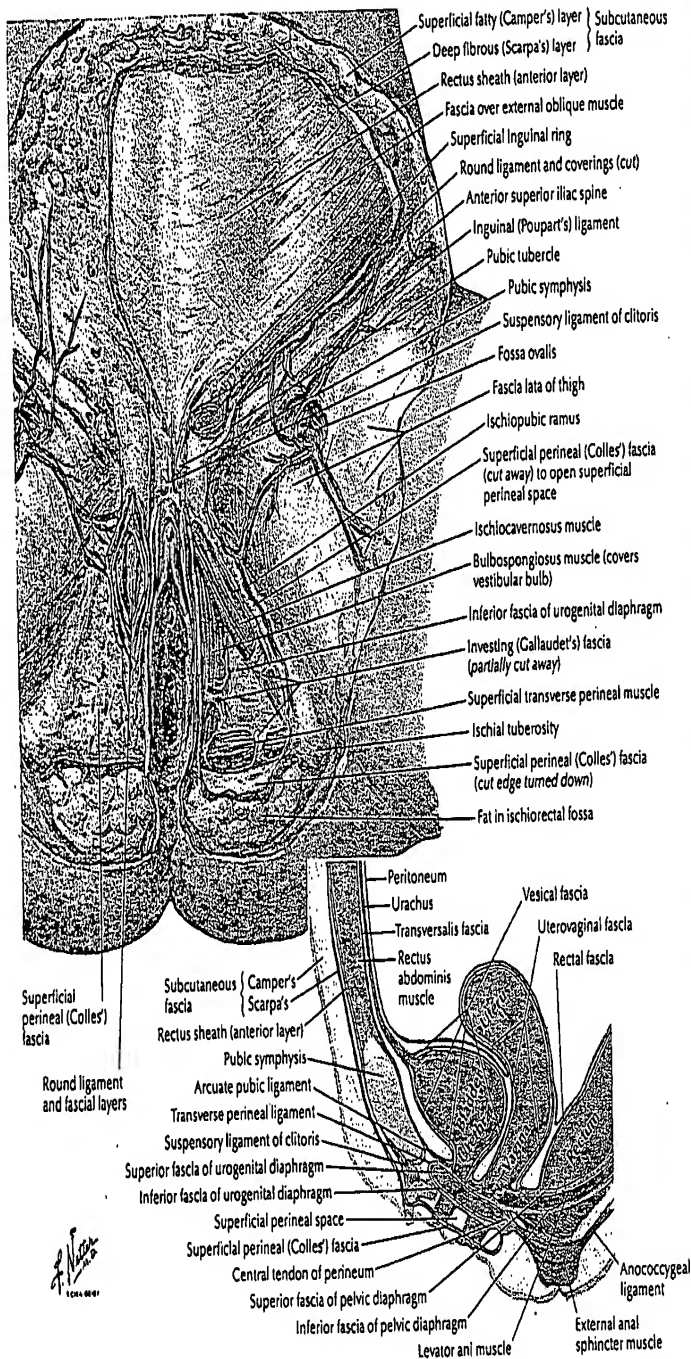
PELVIS AND PERINEUM

Urinary Bladder: Orientation and Supports

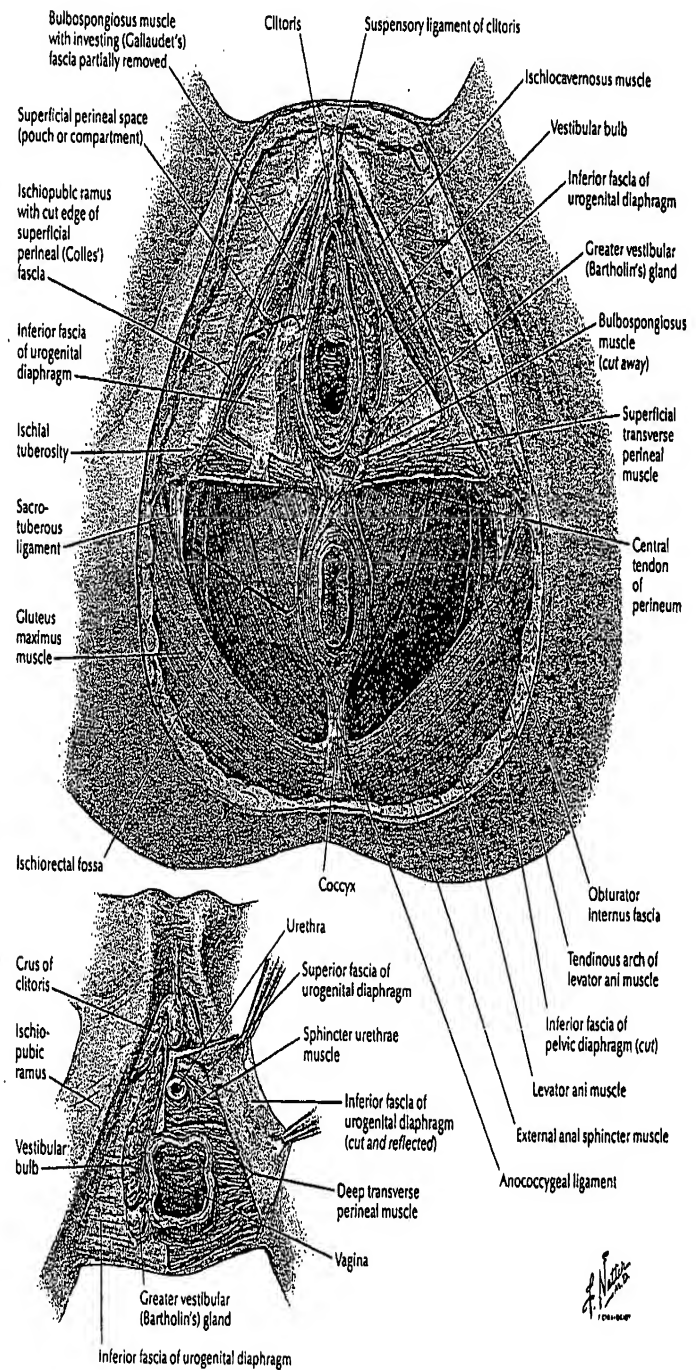


PELVIC FLOOR AND CONTENTS

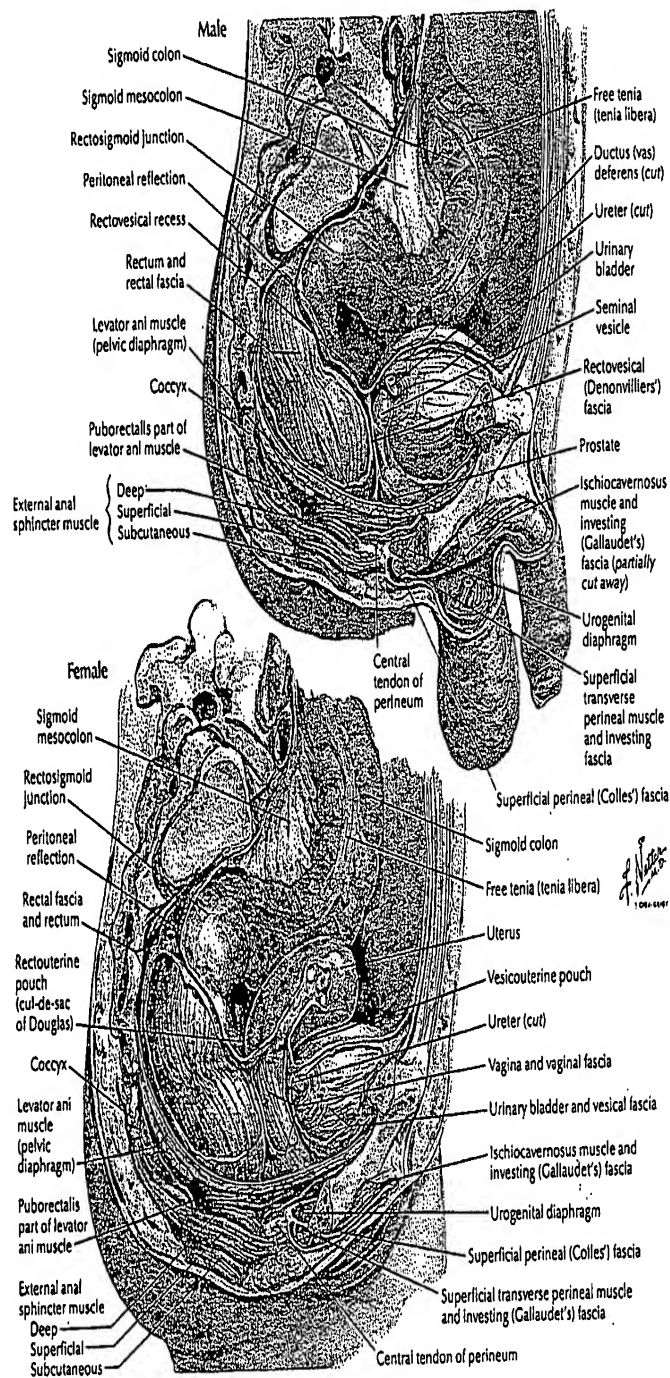
Perineum (Superficial Dissection): Female



Perineum and Urogenital Diaphragm: Female

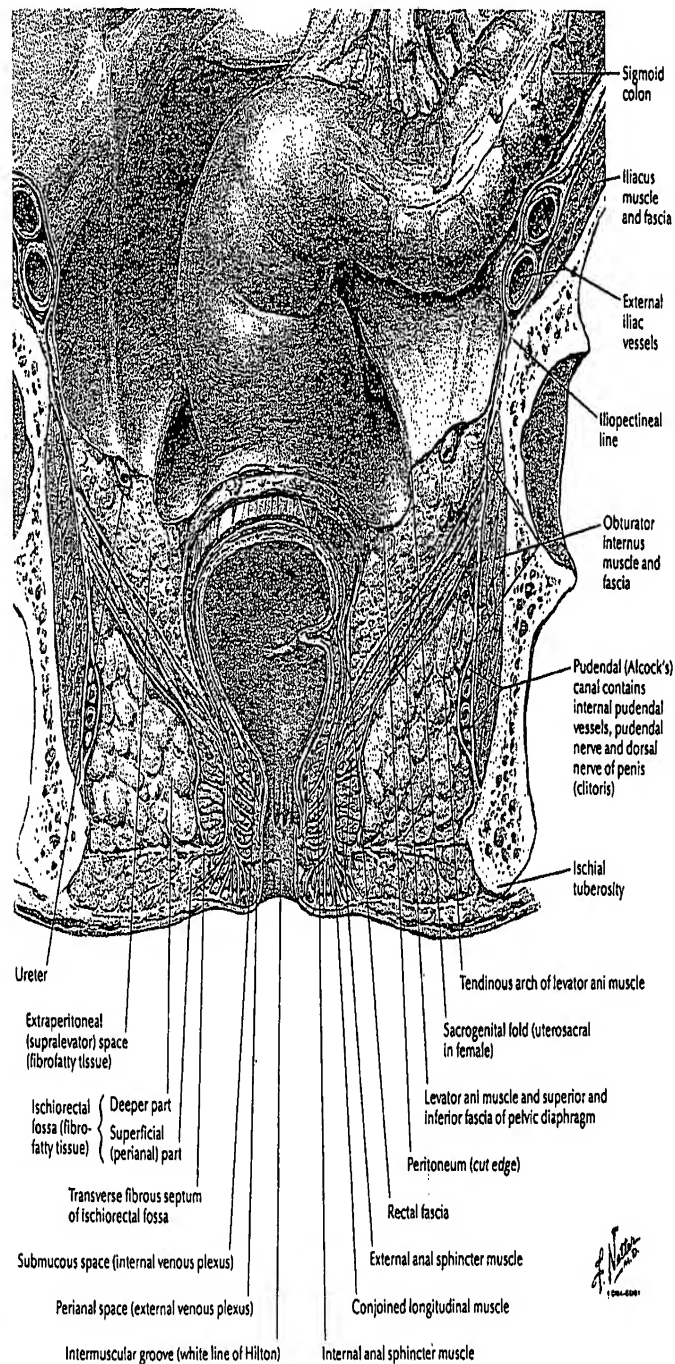


Rectum In Situ: Female and Male



Ischioanal Fossa

SEE ALSO PLATES 301, 385, 386, 387, 388



Bony Attachments of Muscles of Hip and Thigh: Anterior View

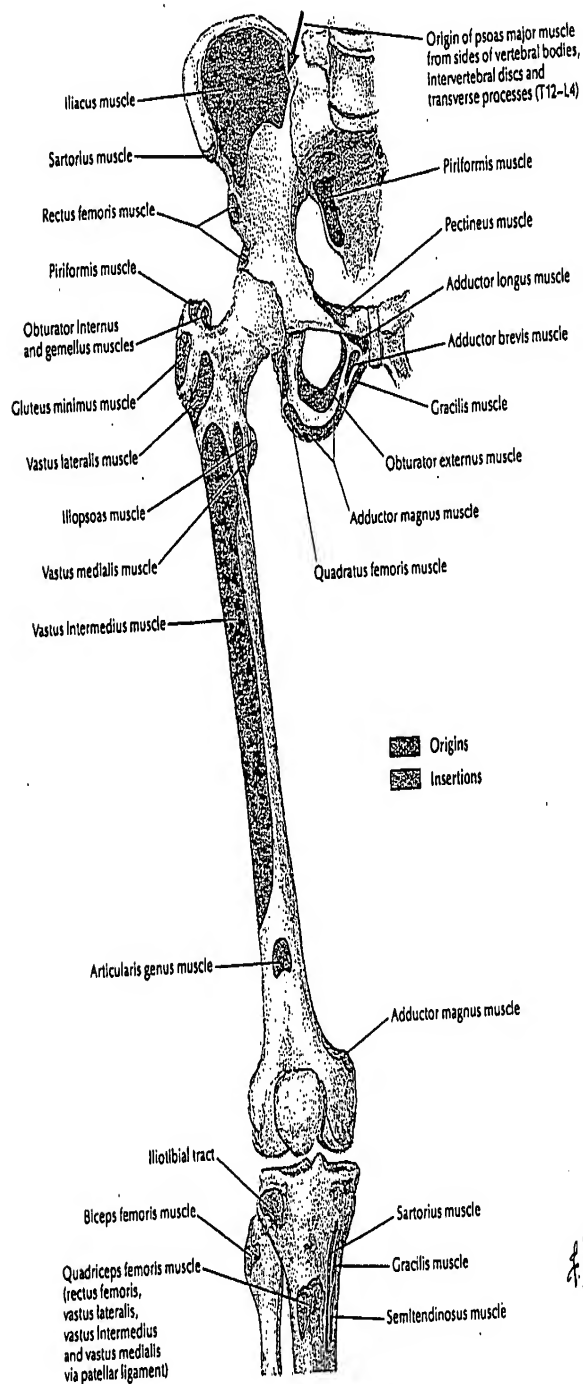
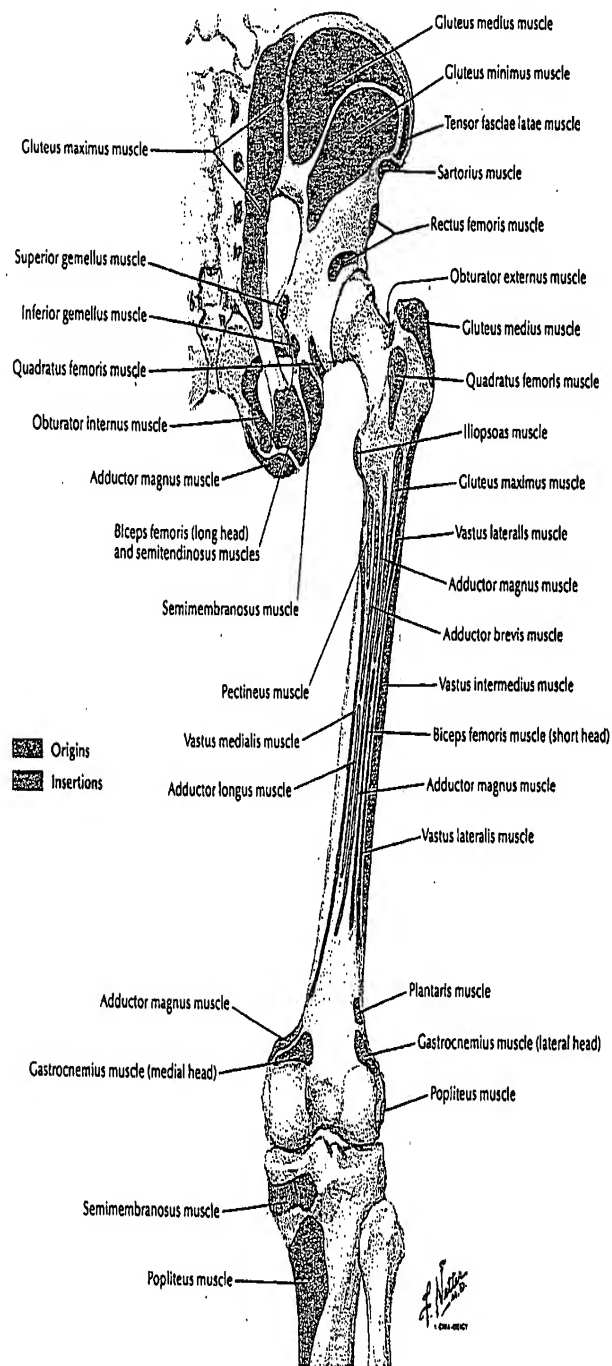


PLATE 460

LOWER LIMB

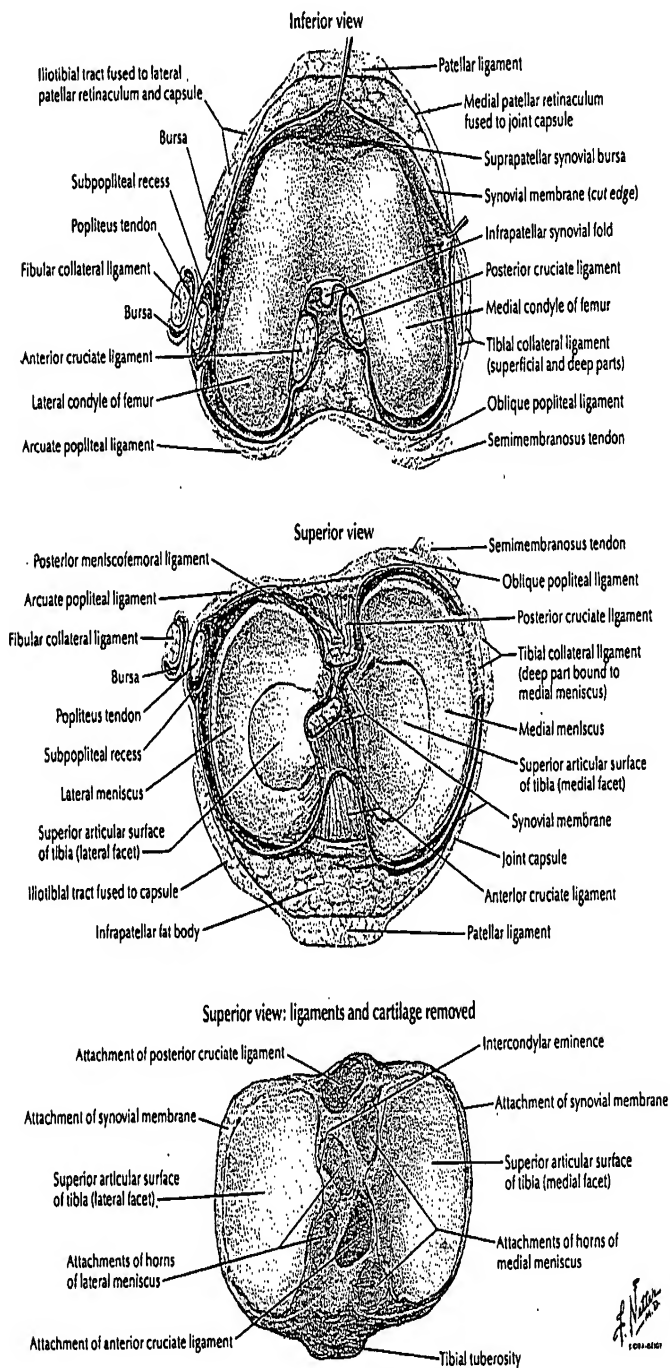
Bony Attachments of Muscles of Hip and Thigh: Posterior View



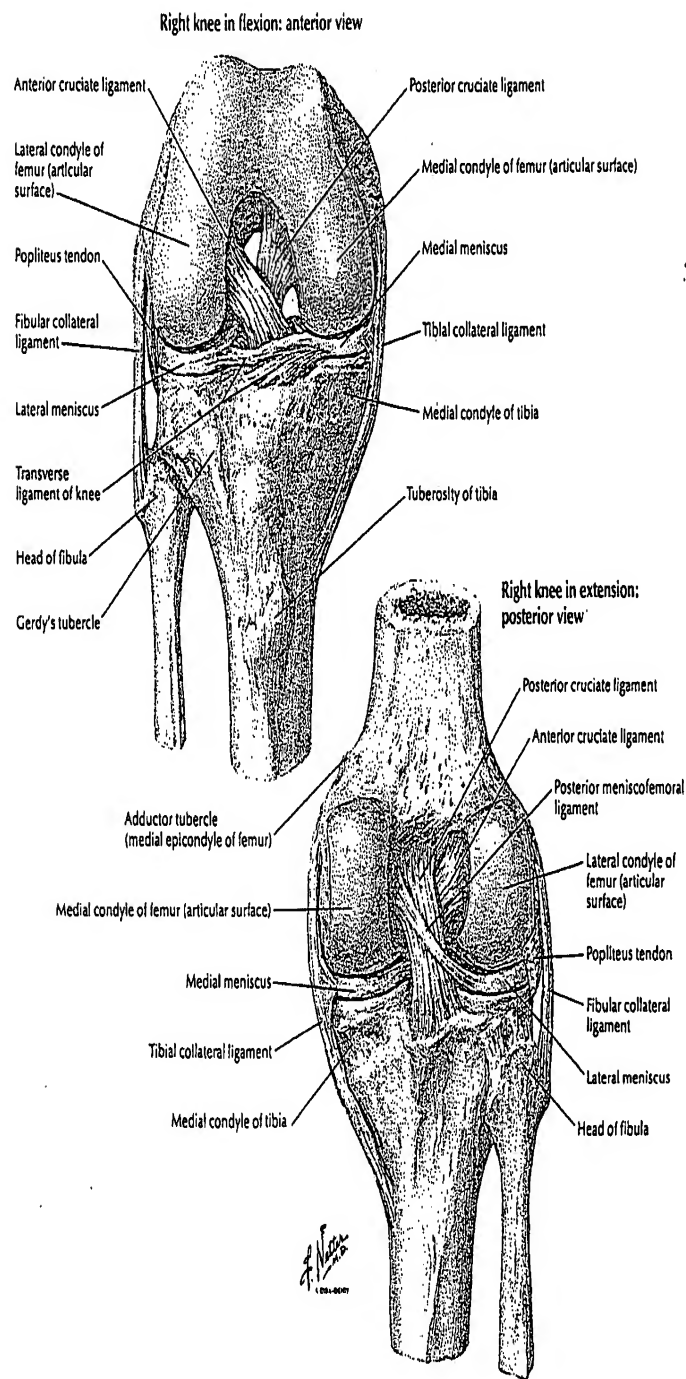
HIP AND THIGH

PLATE 461

Knee; Interior



Knee: Cruciate and Collateral Ligaments



APPENDIX C

APPENDIX C

Description of the anatomy where the mesh of the present invention is inserted

Compare the vagina to a cylinder. The base is open, the top is closed by the uterus in a part we call the cervix (or uterine neck). The front half of the vaginal surface (vaginal wall) is in contact with the bladder and the posterior half with the rectum.

Prolapse of the female pelvic organs through the vagina can be categorized as of the anterior, middle or posterior segment.

Prolapse of the anterior segment occurs when the anterior wall of the vagina and the bladder descend so as to occupy the interior of the vagina. This situation is often accompanied by urinary incontinence, which can also occur without prolapse.

Prolapse of the middle segment occurs when the cervix or uterine neck slide inside the interior of the vagina. This is always accompanied by prolapse of the intestine (enterocele) which occupies the vagina together with the uterus.

Prolapse of the posterior segment occurs when the vaginal wall and the rectum descend to occupy the interior of the vagina.

Prolapse is classified in 4 degrees: 1st degree, when the organs have fallen but remain inside the vagina to 4th degree when the organs protrude completely outside the vagina.

Each of the three types (anterior, posterior and middle) can exist alone or combined with one or both of the other types.

The combined situation is defined as total prolapse of the pelvic organs. It produces a major disturbance and is the most difficult prolapse to correct.

Prolapse occurs when the muscles and the ligaments attached to the organs in question become lax. The principal structures involved are the urethro-pelvic ligaments (the anterior vaginal segment), the cardinal ligaments (the middle vaginal segment), and the utero-sacral ligaments (posterior vaginal segment).

Comparing Landgrebe with the present invention

	Landgrebe	Present invention (Nicita)
Device	Implant for suspension of the urinary bladder in cases of incontinence of urine in women.	Device for the surgical treatment of female prolapse.
Surgical indication	This is a device to correct only incontinence and anterior (bladder) prolapse.	This device corrects total vaginal prolapse, that is of the bladder, uterus and intestine.
Method of Insertion of the Device	This device is surgically inserted through an incision in the abdominal wall (Pfannestiel's incision). The device is placed under the bladder and in front of the uterus.	This device, by contrast, is inserted through the vagina. It is placed under the bladder, around the cervix (uterine neck), and under the intestine (enterocele).
Anchoring Mechanisms	The device creates a support plane under the bladder. The anterior bridles of the implant are drawn retrosymphysally with no stitches or additional system of support. The rear bridles are fixed to the right and left ligamentum pubicum (that is located in front of the uterus) and then are pulled through the rectus muscle and apposed crosswise over this. The device does not modify the position of the uterus and of the intestine.	The inventiveness of this device is that supplies an anterior, posterior and a mid-zone support for descended organs. The anterior portion of the device supports the prolapsed bladder. It is fixed bilaterally with stitches through its front arms (bridles) to the arcus tendineous levator ani (the bridles substitute the support function of the natural urethro-pelvic ligaments). The central portion is placed around the uterine cervix to support the uterus (it substitutes the natural function of the cardinal ligaments). The posterior portion of the device, located behind the uterus restores the prolapsed bowel (enterocele) to its correct anatomical position. It is fixed

		bilaterally with stitches through the rear arms (bridles) to the sacrospinous ligament (it substitutes the natural support function of the sacro-uterine ligaments).
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Conclusion:

The present invention as defined in the pending claims has a significantly different shape and structure from Landgrebe et al. Also,

Langrebe's device is much more limited in function than the applicant's. It supports only the bladder. Its fixation system is in front of the uterus where it is anchored to the pubic ligament. Therefore, its utility is restricted to cases of incontinence and prolapse of the bladder. Moreover, the structure of Langrebe's device cannot be adapted to use for correcting total prolapse.

The Applicant's device provides a much more complex support. It is ideated to correct total, that is combined prolapse, in other words, of the bladder and uterus and intestine. The anterior anchorage system to the arcus tendineus, the middle system to the cardinal ligaments, and the posterior system to the sacro spinous ligaments make the applicant's device completely different from Langrebe's.